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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,116	08/18/2006	Hideaki Umayama	079088-0102	2809
22428	7590	12/21/2010	EXAMINER	
FOLEY AND LARDNER LLP			CLOW, LORI A	
SUITE 500			ART UNIT	PAPER NUMBER
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WASHINGTON, DC 20007			1631	
MAIL DATE		DELIVERY MODE		
12/21/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,116	<b>Applicant(s)</b> UMEYAMA ET AL.
	<b>Examiner</b> LORI A. CLOW	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 October 2010.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11,13-21 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,18,19,28 and 29 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7,10,11,13-17,20,21,23-27 and 30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 August 2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of Patent Office Citation (PTO-222)

4) Interview Summary (PTO-413)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date: \_\_\_\_\_

3) Information Disclosure Statement(s) (PTO/SB/08)

5) Notice of Informal Patent Application

Paper No(s)/Mail Date: \_\_\_\_\_

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' response, filed 13 October 2010, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11, 13-21, and 23-30 are currently pending.

Claims 8, 9, 18, 19, 28, and 29 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 April 2011.

It is noted that Applicant has stated that because claims 9, 19, and 29 were listed as generic in the Office Action of 24 March 2010, they should be examined. This was clearly a typographical error in the Restriction Requirement, as claims 9, 19, and 29 depend from withdrawn claims 8, 18, and 28 respectively and are hereby also withdrawn.

Claims examined herein include 1-7, 10, 11, 13-17, 20, 21, 23-27 and 30. It is noted that Applicant has claim 31 listed as pending in the Response filed 13 October 2010 (Response, page 14, line 8). However, the claim listing has claim 31 as "cancelled", as well as page 15, line 13, which indicates that claim 31 is "cancelled". The claim will herein be treated as "cancelled".

Claims 12, 22, and 31 are cancelled.

#### **Specification**

The objections to the Specification have been withdrawn in view of the amendments submitted 13 October 2010.

### **Claim Objections**

The objections to the claims have been withdrawn in view of the claim amendments submitted 13 October 2010.

### **Sequence Compliance and Drawings**

The Sequence Listing submitted 13 October 2010 has been entered. The case is now in Sequence Compliance and as such, the objections to the Drawings are hereby withdrawn.

### **Claim Rejections - 35 USC § 101-Non-statutory Subject Matter**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 13-17, and 20 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 11, 13-17 and 20 are drawn to a method which screens for a ligand that binds to a protein when coordinate data of a protein of a single chain or plural chain is given. The claims have been amended to recite, at step 1, that a data selecting step is performed with a computer.

In accord with the decision in *In re Bilski* (cited below), a claim to a process or method must meet the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract

concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (Gottschalk v. Benson, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, the method claims are not so tied to another statutory class of invention because the method steps that are critical to the invention are "not tied to any **particular apparatus or machine**" nor do the steps provide a transformation of data and therefore do not meet the machine-or-transformation test as set forth in In re Bilski 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

It is noted that the first method step of selecting coordinate data is done with a computer. However, the machine recited in this case does not meaningfully limit the execution of the steps, as any generic machine could perform the method step. Further, the involvement of the recited machine is nominally related to the performance of the steps because it is merely a data gathering step. As such, the claims remain non-statutory.

It is noted that the rejections over claims 21-27, 30 and 31 have been withdrawn in view of the claim amendments.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10, 11, 13-17, 20, 21, 23-27 and 30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11, and 21 recite, "post-structural-change protein coordinate data selecting unit that effects structural change in consideration of dynamic behavior". It is unclear as to what is intended by this limitation. Does the selecting unit make a structural change in the protein based on protein dynamic behavior, for example? Clarification through clearer claim language is requested.

Claims 5, 15, and 25 recite, "reevaluating unit that executes the interaction function calculating unit". It is unclear if the reevaluating unit interacts with the calculating unit or if some other function occurs. Please correct claim language.

It is noted that all other outstanding rejections under 35 USC 112, 2<sup>nd</sup> paragraph have been withdrawn in view of the claim amendments and in view of Applicant's arguments.

#### ***Response to Applicant's Arguments***

1. Applicant points to support for "post-structural-change" at paragraphs [0165] and [0166]. These passages teach that one ligand is selected from a compound database, and a 3D structure data of the ligand is acquired. Also a 3D structure data of a target protein is acquired. Then, using an induced-fit parameter reflecting induced-fit to prepare plural sets of protein coordinate data after structural change one set of post-structural protein coordinate data is randomly chosen. The recited passages do not teach, however, the limitations as are instantly

claimed. The recited passages do not teach how a selecting unit effect structural change in consideration of dynamic behavior nor do the claims reflect the recited passages. As such, the claims remain unclear. Clarification through clearer claim language is requested.

2. Applicant provides no argument with regard to the rejection of claims 5, 15, and 25, recited above. The rejection is therefore maintained.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-6, and 10 remain rejected under 35 U.S.C. 102(a) as being anticipated by Hammer et al. (Steroids (2003) Vol. 68, pages 329-339; PTO Form 1449 Reference), for the reasons set forth in the previous Office Action and re-iterated below.

The instant claims are drawn to an apparatus, method and program for ligand screening in which coordinate data and induced fit parameter modeling is used to model protein binding;

superposition of a ligand using spatial points is performed; interaction of protein and ligand are calculated' and binding is evaluated.

In regard to the instant claims, Hammer et al. teach a method and system for interactions of glucocorticoids (GC) with ligand-binding domains of the glucocorticoid receptor (GR) using molecular modeling including ligand docking and molecular dynamics simulations (abstract). A ligand binding domain (LBD) was modeled using SURFNET software taking into consideration the free space in the LBD (page 333, column 1). Induced fit procedures were used by molecular dynamics simulation using INSIGHT/DISCOVER software and protein quality was controlled by PROCHECK software that monitored changes (the dynamics) of the binding pocket. Superimposition was employed using 3D QSAR analysis to evaluate the interaction fields between the ligand and receptor. Biological activity was assessed using partial least squares (page 333, column 1-2).

*Response to Applicant's Arguments*

1. Applicant argues that Hammer is completely silent with respect to having a single apparatus comprising several units to perform a distinct action as recited in the present independent claim 1.

This is not persuasive. Hammer et al. teach each of the recited limitations in the above rejected claims, as previously stated. Just because the prior art does not teach a single apparatus (which is not claimed as being a single apparatus) does not vitiate the fact that all limitations are disclosed. As such, the rejection is maintained.

It is noted that the rejection over claims 11, 13-16, 20, 21, 23-26, 30, and 31 have been withdrawn in view of the claim amendments and claim cancellations.

**Rejection over WO 2002/057954**

The outstanding claim rejections over the '954 document have been withdrawn in view of the claim amendments.

**Rejections over Bursavich**

The outstanding claim rejections over US 2003/0190670 (Bursavich et al.) have been withdrawn in view of Applicant's arguments and the claim amendments herein.

**Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 20, 2010  
/Lori A. Clow, Ph.D./  
Primary Patent Examiner  
Art Unit 1631

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